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ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR CONFIRMATION NO. VT0329-US1 10/737,232 12/15/2003 Eric S. Fain 24473 7590 02/10/2006 **EXAMINER** STEVEN M MITCHELL MANUEL, GEORGE C PACESETTER INC PAPER NUMBER ART UNIT 701 EAST EVELYN AVENUE SUNNYVALE, CA 94086 3762

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.   Application   Application				E	
Examiner Dana D. Greene 3762  - The MAILING DATE of this communication appears on the cover sheet with the correspondence address - Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 37 CFR 1.136(a). In or event, however, may a rapply to think grain is desired 340, 600/MTs from the malang date of this communication.  False to reply within the set or extended period for reply will, by datable, cause the application to secone ABANDONED (38 U S. C. § 133). Any reply receded by the Office is that the three monitors and the third willing data of this communication, even if timely flied, may reduce any camera patient with application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quay/e, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 1.22 is/are pending in the application.  4a) Of the above claim(s) is/are allowed.  5) Claim(s) 1.22 is/are rejected.  7) Claim(s) 3.24 is/are rejected to by the Examiner.  10) The drawing(s) filed on 22 January 2006 is/are: a) accepted or b) objected to by the Examiner.  Application Papers  9) The specification is objected to by the Examiner.  10) The drawing(s) filed on 22 January 2006 is/are: a) accepted or b) objected to by the Examiner.  Application Papers  9) The specification is objected to by the Examiner.  10) Some **Collamon** of the priority documents have been received in Application No. 1.1 (Certified copies of the priority documents have been received in Application No. 1.1 (Certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  *See the attached detailed Office action for a list of the cer		Application No.	Applicant(s)		
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2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  5) Notice of Informal Patent Application (PTO-152)	1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ate	O-152)	

## **DETAILED ACTION**

Claims 1-22 remain rejected under the same references disclosed in the Office Action mailed August 25, 2005. The examiner has given full consideration to the Applicant's response filed on November 21, 2005. However, Applicant's arguments and amendments are not persuasive and do not overcome the original rejection.

The examiner has alleged a prima facie case of anticipation with respect to claims 1- 22 and the examiner cites Gillberg et al. (US 6,393,316, hereinafter "Gillberg").

Examiner has cited areas of Gillberg, which suggests excluding one or more of the morphology scores that correspond to the sequence of complexes based upon the analyzed intervals of those complexes as recited in the claims (see col. 8, In. 47-56, Gillberg).

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-22 stand rejected under 35 U.S.C. §102(b) as being anticipated by Gillberg. Gillberg is considered to disclose:

a method comprising: storing intervals corresponding to the sequence of complexes (see col. 5, In. 30-35 and col. 8, In. 47-56, Gillberg). The disclosed method of storing counts is considered to anticipate the claimed method of storing intervals corresponding to the sequence of complexes because both methods aid in the

enhancement of tachycardia classification associated with a sequence of sensed cardiac complexes;

analyzing the stored intervals (*see* col. 8, In. 47-56, Gillberg). The disclosed method of analysis is considered to anticipate the claimed analysis of stored intervals because both derive information from studying the stored EMG segments and use this information to determine whether tachyarrhythmias are present and to distinguish between different types of tachyarrhythmias;

excluding one or more of the morphology scores based upon the analyzed intervals (see col. 8, ln. 47-56 and col. 8, ln. 65 – col. 9, ln. 2, Gillberg). The disclosed discrimination method is considered to anticipate the claimed method of excluding because both operate as morphology discrimination techniques to accurately classify supra-ventricular complexes created as a result of certain conditions.

With reference to claims 2 and 3, Gillberg is considered to disclose the method wherein the rhythm is a tachycardia and wherein the stored intervals are R-R intervals (see col. 8, In. 39-56, Gillberg). The disclosed rhythm and intervals are considered to anticipate the claimed invention because both enhance classification of tachycardias.

Referring to claim 4, the Gillberg reference teaches a method comprising the step of distinguishing between ventricular and supra-ventricular tachycardias based on the excluding step (see col. 2, In. 15-20, Gillberg). The disclosed method anticipates the claimed method of distinction because both advocate the exclusion of short interval complexes from the MD score, thus enabling the morphology discrimination technique

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to more accurately determine whether the tachyarrhythmia is ventricular or supraventricular.

With reference to claims 5-8, Gillberg is considered to disclose:

an analyzing step comprising determining a length of each of the stored intervals and comparing the determined length with a threshold value (see col. 4, ln. 63 – col. 5, ln. 13 and col. 19, ln. 10-20, Gillberg). The disclosed step of analysis is considered to anticipate the claimed step because both utilize the method of analysis to determine whether the length of the current interval is shorter than the threshold and to determine the threshold value.

Referring to claims 9-10, the Gillberg reference teaches a distinguishing step including determining if a predetermined number of complexes of a total number of required complexes (X of Y) have a morphology score greater than a predetermined threshold and includes a step of not altering the value of X or Y associated with the current interval when the current interval length is shorter than the predetermined length (see col. 20, In. 1-30, Gillberg). The disclosed method of rate based detection and EGM morphology is considered to anticipate the claimed method because both employ discrimination techniques for altering or reducing the value of X and Y in relation to the current interval length.

With reference to claims 11-18 and 22, Gillberg is considered to disclose:

means for sensing a sequence of cardiac complexes (see col. 3, In. 65 – col. 4,

In. 11, Gillberg). The disclosed sensing electrode is considered to anticipate the

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claimed sensing means because both are used to detect electrical activity in the ventricles:

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means for measuring and storing a sequence of R-R intervals between successive complexes, each interval corresponding to a subsequent complex; means for detecting a tachycardia based on the measured intervals; means for analyzing the stored intervals when the tachycardia is detected; means determining whether a selected one of the stored intervals is shorter than a predetermined length; means for ignoring the complex corresponding to the selected interval if the length of the selected interval is shorter than the predetermined length (see col. 8, In. 10-56, Gillberg). The disclosed basic mechanism is considered to anticipate the claimed means for measuring and storing because both use information derived from the analysis of stored EMG segments to determine whether tachyarrhythmias are present and to distinguish between different types of tachyarrhythmias based on predetermined length:

means for calculating a morphology score based on a comparison to a template for at least each complex not ignored; and means for classifying the tachycardia based on the morphology scores of complexes not ignored (see col. 8, ln. 47-56 and col. 8, ln. 65 – col. 9, ln. 2, Gillberg). The disclosed discrimination devices considered to anticipate the claimed calculating means because both operate using morphology discrimination techniques to accurately classify supra-ventricular complexes created as a result of certain conditions.

Referring to claim 19, the Gillberg reference teaches a method for improving classification of a tachycardia, the tachycardia being associated with a sequence of

complexes, each complex having a calculated morphology score, comprising the steps of: storing intervals corresponding to the sequence of complexes; analyzing the stored intervals; and excluding one or more of the morphology scores based upon the analyzed intervals (see col. 5, In. 30-35 and col. 8, In. 47-56, Gillberg). The disclosed method of storing counts is considered to anticipate the claimed method of storing intervals corresponding to the sequence of complexes because both methods aid in the enhancement of tachycardia classification associated with a sequence of sensed cardiac complexes. Gillberg discloses the step of analyzing the stored intervals (see col. 8, In. 47-56, Gillberg). The disclosed method of analysis is considered to anticipate the claimed analysis of stored intervals because both derive information from studying the stored EMG segments and use this information to determine whether tachyarrhythmias are present and to distinguish between different types of tachvarrhythmias. Finally, the Gillberg reference teaches the step of excluding one or more of the morphology scores based upon the analyzed intervals (see col. 8, ln. 47-56 and col. 8, In. 65 – col. 9, In. 2, Gillberg). The disclosed discrimination method is considered to anticipate the claimed method of excluding because both operate as morphology discrimination techniques to accurately classify supra-ventricular complexes created as a result of certain conditions.

Referring to claims 20-21, Gillberg is considered to disclose:

Comparing the stored intervals to an interval threshold and classifying a tachycardia as ventricular or supra-ventricular by analyzing the morphology scores not included (see col. 4, In. 63 – col. 5, In. 13 and col. 19, In. 10-20, Gillberg). The

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disclosed step of analysis is considered to anticipate the claimed step because both utilize the method of analysis to determine whether the length of the current interval is shorter than the threshold and to determine the threshold value. Referring to the step of classifying, Gillberg operates using morphology discrimination techniques to accurately classify supra-ventricular complexes created as a result of certain conditions (see col. 8, ln. 47-56 and col. 8, ln. 65 – col. 9, ln. 2, Gillberg).

## Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 86 6-217-9197 (toll-free).

Dana D. Sheene

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